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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,677	01/15/2002	Deanc Louis Falcone	50229-295	2298

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EXAMINER

KRUSE, DAVID H

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/045,677	FALCONE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	David H Kruse	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 01 April 2004.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 14-25 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-13 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 1/15/2002 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

## DETAILED ACTION

### ***Election/Restrictions***

1. Applicant's election with traverse of Group I, claims 1-13, in the reply filed on 1 April 2004 is acknowledged. The traversal is on the ground(s) that the claims represent a single inventive concept in that in the various methods there is a common thread in that the method steps involve causing random integration of enhancer containing T-DNA into a plant genome and screening the resulting calli (page 2 of the Response). This is not found persuasive because as stated in the previous Office action, each method comprises distinct method steps and different end products. Group I produces plant genetic material, Group II produces information about a metabolite of interest and Group III produces information about a product of secondary metabolism.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 14-25 are withdrawn from further consideration pursuant to 37 CFR § 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 1 April 2004.

3. This application contains claims 14-25 drawn to an invention nonelected with traverse in the reply filed on 1 April 2004. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR § 1.144) See MPEP § 821.01.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR § 1.48(b) if

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one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR § 1.48(b) and by the fee required under 37 CFR § 1.17(i).

***Information Disclosure Statement***

5. The information disclosure statement filed 6 February 2003 fails to comply with the provisions of 37 CFR §§ 1.97, 1.98 and MPEP § 609 because the references are incomplete, see in particular 37 CFR § 1.98(b)(5). It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR § 1.97(e). See MPEP § 609 ¶ C(1).

***Drawings***

6. New corrected drawings are required in this application because the Examiner considers the drawings as originally filed informal. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

***Specification***

7. The specification is objected to because the incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. See page 14, paragraph 57, lines 3, 4, 7 and 8 and page 17, paragraph 67, line 4. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

8. The disclosure is objected to because of the following informalities: In the first line on page 1, 1<sup>st</sup> paragraph, "priority from" should read -- benefit of --. Appropriate correction is required.

***Double Patenting***

9. Applicant is advised that should claim 10 be found allowable, claim 11 will be objected to under 37 CFR § 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

***Claim Rejections - 35 USC § 112***

10. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

11. Claims 1-13 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At claim 1, line 10, "said clonal cultures" lacks proper antecedent basis within the claim.

At claim 3, line 2, "a regulatory gene" is indefinite because it is unclear what the metes and bounds of this limitation are.

Claims 2 and 4-13 are also indefinite because they do not obviate the indefiniteness of claim 1.

***Claim Rejections - 35 USC § 102***

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1-4 and 6-9 are rejected under 35 U.S.C. § 102(b) as being anticipated by Fritze et al (1995, Methods in Molecular Biology Vol 44, Agrobacterium Protocols, Eds K.M.A. Gartland and M.R. Davey, Humana Press Inc. Totowa, New Jersey, pages 281-294).

Fritze *et al* disclose a method of identifying plant genetic material whose actions cause increased production of a plant metabolite or metabolism of interest comprising transforming tobacco protoplast with a T-DNA construct comprising a CAMV 35S promoter sequence, growing said protoplast to the stage of callus cultures, sampling said callus cultures, analyzing said samples to identify the callus cultures that produce the metabolite of interest and isolate and identify the plant genetic material stimulated by the enhancer-containing T-DNA genetic element (see pages 287-290). The limitation "sampling" has been read broadly and is deemed to encompass the regeneration of plantlets disclosed by Fritze *et al* (page 289). The limitation "analyzing" has been read broadly and is deemed to encompass the selection method disclosed on page 282, 3<sup>rd</sup> paragraph, "Selection can be carried out by scoring the ability of transgenic cells to grow under specific selective conditions...We have produced mutant cell lines able to grow either in the absence of auxin or cytokinin". The limitation "is a regulatory gene" at claim 3 has been found to be indefinite, in the instant rejection it is read as a growth regulatory gene, i.e., regulates auxin or cytokinin production. At claim 4, line 3, "pharmacological properties" has been read as an intended use limitation which does not distinguish the claimed method from that disclosed by Fritze *et al*.

***Claim Rejections - 35 USC § 103***

14. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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15. Claim 5 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Fritze *et al* (1995, Methods in Molecular Biology Vol 44, Agrobacterium Protocols, Eds K.M.A. Gartland and M.R. Davey, Humana Press Inc. Totowa, New Jersey, pages 281-294) in view of Browning *et al* (1982, Br. J. Pharmac. 77:487-491).

The teachings of Fritze *et al* are discussed above.

Fritze *et al* do not teach a method of detecting metabolites via a radioligand displacement assay.

Browning *et al* teach a method of detecting opiate metabolites using a radioligand displacement assay (pages 489-490).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the teachings of Fritze *et al* using the radioligand displacement assay taught by Browning *et al* to detect a metabolite of interest. Opiates are highly desirable "pharmacological" compounds produced by plants. Given the success of Fritze *et al* in using a T-DNA tagging method to increase the production of metabolites in a tobacco plant, one of ordinary skill in the art at the time of Applicant's invention would have had a reasonable expectation of success in applying the method to a plant in the poppy family which produces opiates as metabolites of interest and using the method of Browning *et al* to analyze samples to identify callus cultures and subsequently isolate and identify plant genetic material.

***Conclusion***

16. Claims 10-13 are free of the prior art, which neither teaches nor suggests using a method of T-DNA tagging to identify plant genetic material from plants that produce nicotinic acetylcoline agonist.
17. No claims are allowed.
18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (571) 272-0804. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-0547.

  
*David H. Kruse*  
AV 1638

David H. Kruse, Ph.D.  
11 June 2004